

PCN178

BURDEN OF HOSPITALIZATION IN PATIENTS WITH ADVANCED LUNG CANCER IN THE UNITED STATES

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OBJECTIVES: To assess the burden of hospitalization in advanced lung cancer patients in the United States. **METHODS:** Oncologists (N=101) actively involved in management of advanced lung cancer in United States were invited to participate in a lung cancer disease specific program. Each consenting physician was asked to complete patient record forms for 12 advanced (stage IIIB/IV) lung cancer patients seen in their practice and receiving 1st, 2nd or 3rd line of therapy for advanced lung cancer. The study period extended from Oct- Dec 2011. Data on hospitalization that included reasons of hospitalization and the length of stay (LOS) over the past year was provided by physicians from patient records. **RESULTS:** Majority of the patients (N=1200) were male (56%), Caucasian (71%) and Stage IV (78%), with an average age of 65 years. Hospitalization records were obtained for 93% (n=1110) of the patients among which 22% (n=248) of the patients ≥1 hospitalization events in the previous year with an average (SD) LOS of 4 (2.4) days and a median LOS of 3 days. The reasons reported for the 293 hospitalization events were disease symptoms (61%), surgery (19%) and therapy side effects (43%). The LOS for surgery related hospitalization (n=57) ranged from 1-12 days (mean (SD): 6 (2.9) days; median: 5 days). Among disease symptoms reported as reasons for hospitalization, the most frequent were pain (51%), dyspnea (47%) and cough (47%) respectively. Among side effects reported as reasons for hospitalization anemia (25%), febrile neutropenia (21%) and fatigue (20%) were most frequently reported. **CONCLUSIONS:** Burden of hospitalization in advanced lung cancer patients is significant in the United States. Innovative therapies with favorable side effect profile that also alleviate need for surgery and are effective in improving lung cancer symptoms could help significantly in decreasing hospitalization burden in advanced lung cancer patients.

PCN179

PERCEPTION OF COUNTRY-SPECIFIC HEALTH CARE REFORM AND CONSIDERATION OF REAL WORLD EVIDENCE IN ROUTINE PRACTICE: SURVEY OF ONCOLOGISTS IN EUROPEAN UNION, UNITED STATES, CHINA AND BRAZIL

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OBJECTIVES: To assess oncologist perception of their country-specific health care reforms and the consideration of 'Real World Evidence' (RWE) when prescribing medications in the EU, US, China and Brazil. **METHODS:** A multi-country cross-sectional survey was conducted in top-5 EU countries (UK, Germany, Spain, France, Italy), US, Brazil and China in February 2013 using an online physician panel in the respective geographies; oncologists were randomly selected for survey participation to be geographically representative in each country. Surveys assessed the oncologist perceptions of health care reforms in their respective countries, and their consideration of the following, when prescribing oncology medications: RWE on product effectiveness/safety, patient quality-of-life (QoL) and product cost/patient affordability. Descriptive statistics are reported. **RESULTS:** A total of 257 oncologists participated in the survey. Specialties included: medical oncology-69%, haemato-oncology-11%, radiation-oncology-9%, surgical-oncology-5%, gynecologic-oncology-3%, pediatric-oncology-2%, other-2%. Geographic distribution of oncologists was: SEU-36%, US-33%, China-17% and Brazil-14%. Overall, 40% of oncologists indicated that they were 'not sure whether their country's health care reform is heading in the right direction' (SEU:39%, US:40%, China:44%, Brazil:36%); 38% indicated that they were 'concerned of country's health care reform's implications for them and their practice' (SEU:30%, US:50%, China:44%, Brazil:19%); 23% indicated that the health care reform 'did not have enough focus on RWE needs and cost-effectiveness of medications' (SEU:16%, US:24%, China:37%, Brazil:19%). When prescribing oncology medications, consideration of following attributes 'all the time' differed across the countries (Overall/SEU/US/China/Brazil): RWE on product effectiveness and safety (37%/29%/38%/47%/42%), patient QoL (54%/48%/59%/42%/69%), product cost/patient affordability (23%/15%/20%/42%/28%). **CONCLUSIONS:** Across markets, a significant proportion of oncologists raised concerns regarding their country-specific health care-reforms, and between one-third and half of the oncologists reported considering RWE data while prescribing medicines. As the health care reforms evolve in the studied countries, its actual implications warrant closer scrutiny to alleviate physician concerns and improve care delivery and outcomes.

PCN180

THE EXPECTED HEALTH ECONOMIC VALUE OF USING CIRCULATING TUMOR CELLS TO PERSONALIZE CANCER TREATMENT

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OBJECTIVES: Research has shown that circulating tumor cells (CTCs) in the blood can give valuable information about the prognosis and treatment options in oncology. A new approach, CTC therapeutic apheresis (CTCtrap) is being developed for use in breast and prostate cancer. At the moment it is not clear where in the diagnostic track CTCtrap could be of most value. The goal of this study is to estimate the health impact of using CTCtrap in 1) screening for breast cancer; 2) early staging of tumors; and 3) therapy response monitoring. **METHODS:** A systematic literature study and experts' interviews were used to document the diagnostic track in breast cancer. Headroom analysis and early health economic modelling was used to estimate the health impact of implementing CTCtrap at the three different purposes. **RESULTS:** Dependent on the assumption of sensitivity, the CTCtrap could decrease the total screening costs. Yet, it is expected that this application only has limited clinical utility. In the early staging, the CTC trap can replace the currently used FDG-PET-CT. The CTCtrap could provide additional staging information and therapy can be selected more specifically, eliminating unnecessary costs. Finally, CTCtrap as a monitoring

tool enables personalising therapy by analysing discordance in hormone receptor (HR) and Human Epidermal Growth Factor Receptor 2 (HER2) expression in CTCs compared to solid tumors in metastatic breast cancer patients. It is estimated that in total 4,41% of metastatic breast cancer patients could be treated in a more efficient way, leading to increase in progression free survival of 5,59 months. Increase in clinical utility is expected to be the most important consequence of this implementation option. **CONCLUSIONS:** CTCtrap as a monitoring tool is expected to be of most value. In this stage, a more appropriate prescription of expensive therapies can be administered to patients who are sensitive for these therapies.

PCN181

THE IMPACT OF AMNOG ON ONCOLOGY DRUGS

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OBJECTIVES: The implementation of the 2011 German health care reform (AMNOG) introduced pricing mechanisms which oblige newly launched patented drugs to undergo an early evaluation of their additional benefit by IQWiG, with a final resolution given by the G-BA. Medicines which demonstrate an incremental therapeutic benefit versus an appropriate therapeutic comparator – with an innovation score ranging from 1 to 4 – enter the preferable pricing negotiation system; those failing to prove benefit – a score of 5 or 6 – are relegated to the reference pricing system. The study aims to discern how oncology drugs, which began the process of benefit assessment during 2012, fared under the new system, and whether survival data influenced the decisions. **METHODS:** We reviewed both IQWiG and G-BA documents relating to eight cancer drugs assessed during 2012 to determine whether each drug received a positive or negative early benefit assessment. Reasons for each specific decision were then investigated. **RESULTS:** Of the five drugs qualifying for pricing negotiations, vemurafenib (Roche, Switzerland) was the only drug to demonstrate a statistically significant improvement in overall survival (OS) at the time of assessment. It received the highest innovation score of the five qualifying drugs. For the three drugs not qualifying for pricing negotiations, the G-BA cited an incomplete dossier or issues with comparators as the reason for rejection. **CONCLUSIONS:** Although OS is considered the favoured clinical endpoint, the study results show that this endpoint is not always necessary to enter pricing negotiations. However, when OS is not proven, the G-BA often gave a positive assessment to only a small portion of eligible patients. Additionally, two of the qualifying drugs were orphan drugs, which entails exemption from the need to prove an additional benefit if annual sales are below EUR50 million.

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DEVELOPING PERSONALIZED MEDICINE DRUGS - INCENTIVES FOR PHARMACEUTICAL COMPANIES

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OBJECTIVES: Stratification of oncology drug therapy by genetic marker diagnostics can reveal additional patient benefit but also might influence the development process of drug manufacturers. The objective of this study is to identify and describe the most important incentives for pharmaceutical companies to develop personalized medicine drugs. **METHODS:** To describe the main factors influencing the decision-making process in the development of personalized medicine drugs. The main factors influencing the process and their priority ranking were determined by structured expert interviews with pharmaceutical companies, test manufacturers and other key stakeholders such as regulatory bodies, reimbursement decision makers and payers. **RESULTS:** In contrast to small companies big international companies constantly look for suitable companion diagnostic tests to select subgroups of high responder. The most important key factor for market success is the extent of clinical efficacy in comparison with competitors respectively the current treatment standard. Stratification of patient populations according to treatment response or frequency of adverse events using biomarker is regarded to increase clinical efficacy of the target indication. The test performance is important due to unsolved safety issues although not regarded as crucial for the success of the drug. In contrast to other stakeholders pharmaceutical companies did not consider personalized medicine to relevantly decrease development costs or marketing efforts respectively to increase the price potential for new drugs. A low prevalence of the remaining patient population after testing is not seen as a factor which might lead to a stop of the development of a new drug by pharmaceutical companies. **CONCLUSIONS:** Genetic stratification is seen as a breakthrough in cancer therapy by pharmaceutical companies and physicians. Due to the current need for improvement of approval and reimbursement processes for personalized medicine approaches in oncology especially in Europe future sales are more difficult to predict.

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ARE ICER THRESHOLD VALUES MALLEABLE? THE CASE OF LIFE-EXTENDING CANCER TREATMENTS AT THE END OF LIFE

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OBJECTIVES: HTA bodies treat end of life (EOL) conditions differently than other conditions? And if so does this depend on whether they have a specific policy for EOL? **METHODS:** NICE's website was searched for single technology appraisals of cancer drugs evaluated between January 2009 to May 2013 for which NICE's supplementary advice for EOL treatments was accepted. The websites of other agencies – SMC (Scotland), TLV (Sweden), PBAC (Australia), pCODR (Canada, except Quebec) and INESSS (Quebec) – were searched for HTAs of the drugs deemed to have met NICE's EOL criteria. A literature search was performed to identify estimated willingness-to-pay ICER threshold values (WTP-ICER) for each agency and to determine if the agency has a specific EOL policy. These were compared against the final ICERs of the retained HTAs. **RESULTS:** Seventeen drugs were identified for which NICE's EOL supplementary advice was accepted. Several of these were also evaluated by other agencies, but only those with final ICERs below the WTP-ICER were retained: